

Applicant : Neil H. Bander
Serial No. : 09/357,704
Filed : July 20, 1999
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Attorney's Docket No.: 10448-184002 / MPI1996-
037P2RDV1A(RCE); CRF D-1912I

REMARKS

Claims 69-80, 124-127, 129, 130, 136-173 and 186-189 are pending. Claims 83-94, 132-135 and 174-185 have been cancelled. Claims 69, 124, 125, 126, 127, 129, 130, 136-139, 153, 156, 159, 160 and 186-189 have been amended. Support for the amendments to the claims can be found, for example at page 27, lines 26-35 and page 28, lines 6-10. No new matter has been added.

The specification has been amended, thereby obviating the Examiner's objection.

Applicants also thank the Examiner and his supervisor for the telephone interview in December 2003. Applicants agree with the Examiner's summary that agreement was reached with regard to Israeli et al.

Rejection of Claims 69-80, 83-94, 124-127, 129-130 and 132-189 Under 35 U.S.C. §112, first paragraph

Claims 69-80, 83-94, 124-127, 129-130 and 132-189 are rejected under 35 U.S.C. §112, first paragraph, for "scope of enablement". The Examiner asserts that Applicant's arguments "fail to distinctly address the scope of the claims with regards to preventative modalities."

Applicants respectfully disagree with this assertion. However, in the interest of expediting prosecution of the application, the claims have been amended to remove the language for preventing or delaying "the development" of prostate cancer. The amendments to the claims obviate this rejection.

Claims 68-78, 83-94, 124-127, 129-130, 132-171 and 174-189 are further rejected under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Examiner asserts that "the suggested claim language of an antibody or antigen binding portion thereof which binds an epitope of prostate specific membrane antigen which is

also recognized by a monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and a J591 monoclonal antibody has no clear support in the disclosure as filed."

Applicants respectfully traverse this rejection. However, in the interest of expediting prosecution of the present application, the claims have been amended to remove this language. The claims, as amended, are directed to an antibody or antigen binding portion thereof which competes for binding to prostate specific membrane antigen with a monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and a J591 monoclonal antibody. The present application clearly provides sufficient description of antibodies that compete for binding to PSMA that a skilled artisan would recognize that applicants were in possession of the claimed invention at the time of filing.

The written description requirement is met if the specification shows that the applicant was in possession of the claimed invention at the time of filing. It is well accepted that "in order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *ad haec verba* support for the claimed subject matter at issue". *Purdue Pharma v. Faulding, Inc.*, 56 USPQ 2d 1481 (Fed. Cir. 2000). Instead what is required is that "the missing descriptive matter must necessarily be present in the ... specification such that one skilled in the art would recognize such disclosure." *Tronzo v. Biomet, Inc.*, 47 USPQ2d 1829 (Fed. Cir. 1998).

Here the claimed invention is a method that uses an antibody having a specific relationship, i.e., it competes with, a specific, disclosed antibody, namely E99, J591, J415 or J533. It is clear that E99, J591, J415 and J533 are disclosed. It is also clear that antibodies that compete with a subject antibody, e.g., one or more of E99, J591, J415 and J533, are disclosed. There are two types of antibodies disclosed in the specification: those that compete for binding with another anti-PSMA antibody, e.g., one of four specific antibodies made, and those that do not compete for binding with the subject antibodies. Specifically, the specification provides in an embodiment where two antibodies were being described that it is preferable, but not necessary, that the second biological agent does not compete for binding with the first. See page 27, lines 26-35 which provides that "the prodrug activator is conjugated with a second biological agent according to the invention, preferably one which binds to a noncompeting site on the

PSMA molecule." (emphasis added). Note that the disclosure is not limited to and does not require a noncompeting antibody, but only that a noncompeting antibody is preferred. In addition, the specification clearly described the preferred noncompeting antibodies and the less preferred competing antibodies and provides what constitutes a competing site and what constitutes a non-competing site by stating that "whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding assays." See page 28, lines 6-10 of the application. Thus, although noncompeting antibodies are preferred, it is clear that competing antibodies are described. Therefore, the concept of having an antibody that competes for binding with the disclosed anti-PSMA antibodies is necessarily part of the disclosure of the present application.

There are four specific antibodies, namely E99, J591, J415 and J533, that are described throughout the application. The application clearly described that any of these four antibodies can be one of the two biological agents. Thus, the application contemplates antibodies that compete or do not compete for binding with any of the four specified antibodies. Competition studies were carried out between E99, J591, J415 and J533 in example 10 at page 37 of the application. The studies were carried out between the enumerated antibodies but those were the only antibodies that were made. It would not be possible to carry out actual experiments on antibodies "in general" or in the abstract. This does not mean that the only competing antibodies disclosed are these four antibodies. These were merely the actual antibodies that were made. Therefore, as indicated by the sections of the application highlighted above, it is clear that there is sufficient description of the claimed invention.

Claims 84, 86, 88, 90, 92, 94, 133, 135, 175, 177, 179, 181, 183 and 185 are also rejected "as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of he claimed invention."

These claims have been cancelled, thereby obviating this rejection.

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For the reasons discussed above, Applicants respectfully request that the Examiner withdraw this rejection.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 4/12/04

A handwritten signature in cursive ink that reads "Laurie Butler Lawrence".

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